IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICIS PHARMACEUTICAL CORPORATION,	)	
Plaintiff,	)	
v.	)	C. A. No. 10-1099-SLR
NYCOMED US INC.,	)	
Defendant.	)	

REPLY BRIEF IN SUPPORT OF DEFENDANT
NYCOMED US INC.'S MOTION TO DISMISS THE COMPLAINT

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I. INTRODUCTION

Medicis' arguments in opposition to Nycomed US Inc.'s ("Nycomed") Motion to Dismiss are illogical and contrary to law. Where there is no Paragraph IV certification for an Orange Book-listed patent, there is simply no basis for an infringement action under section 271(e)(2), or ancillary claims of infringement of that patent. Accordingly, the Court should dismiss Medicis' complaint in its entirety pursuant to Federal Rules of Civil Procedure 12(b)(6) and 12(b)(1).

Although Nycomed believes its Motion to Dismiss should be granted, it respectfully suggests that the Court hold that motion in abeyance until after it has decided Nycomed's co-pending Motion to Transfer. The Court has already transferred Medicis' action asserting infringement of related patents, based on the same Nycomed Abbreviated New Drug Application, to the United States District Court for the Southern District of New York. *See* D.I. 29, Order Granting Motion to Transfer, *Medicis Pharm. Corp. v. Nycomed US Inc. et al.*, Civ. No. 10-419-SLR (D. Del. Mar. 31, 2011). If the Court rules in Nycomed's favor on the transfer motion in this action, then it need not decide the motion to dismiss, and that motion can instead be addressed by the Southern District of New York.

II. ARGUMENT

A. A PARAGRAPH IV CERTIFICATION ON THE '738 PATENT IS NECESSARY TO GIVE RISE TO JURISDICTION UNDER 35 U.S.C. § 271(e)(2).

Medicis' action is solely for infringement of the '738 patent. Because that patent is listed in the Orange Book, and because Nycomed has not made any certification as to that patent, let alone the Paragraph IV certification that serves as the foundation for the entire Hatch-Waxman patent litigation scheme, Medicis' complaint should be dismissed.

Medicis argues that the express language of section 271(e)(2)(A) "provides a jurisdictional 'hook' for **any claim of infringement** so long as an ANDA has been submitted seeking approval of a generic drug prior to the expiration of **any patents covering the brand name product**," and again that the section "provides a jurisdictional basis for the assertion of **any and all patents covering the branded drug or a use of the branded drug**." (Medicis Opp. Br. at 7, 8 (emphasis added).) Medicis' argument, however, overreaches.

As shown in Nycomed's opening brief, the Supreme Court and the Federal Circuit have consistently construed section 271(e)(2)(A) as creating a jurisdictional basis to assert infringement of those patents against which a "Paragraph IV" certification was filed with FDA. Medicis completely ignores these cases. *See, e.g.*, *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1362 (Fed. Cir. 2010); *In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1323 n.4 (Fed. Cir. 2009); *Astrazeneca Pharms. LP v. Teva Pharms. USA, Inc.*, 583 F.3d 766, 769 (Fed. Cir. 2009); *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1078 (Fed. Cir. 2008).

As explained by Chief Judge Rader of the United States Court of Appeals for the Federal Circuit:

> This statutory framework evinces, as the Supreme Court has recognized, that the act of infringement created by section 271(e)(2) is "highly artificial" with a "limited and technical purpose." *Eli Lilly & Co.*, 496 U.S. at 678 . . . . In sum, section 271(e)(2) employs the legal fiction of a defined act of infringement to create case or controversy jurisdiction, thereby enabling a court to promptly resolve any dispute concerning infringement and validity **of the subject patent**. *See Glaxo,* 110 F.3d at 1569.

Zeneca Ltd. v. Mylan Pharms., Inc., 173 F.3d 829, 836 (Fed. Cir. 1999) (concurrence, emphasis added).

Medicis, however, claims that section 271(e)(2)(A) provides a jurisdictional basis so broad as to reach any and all patents covering the branded drug or a use of the branded drug. Medicis is wrong. For example, the statute clearly does not create jurisdiction for patents directed to methods of making drugs—patents that cannot be listed in the Orange Book. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997) (statute "does not provide jurisdiction to hear infringement cases regarding claims directed to methods for making drugs"). Nor does it create jurisdiction over other patents that are likewise not "listable" in FDA's Orange Book, such as patents relating to metabolites of the drug's active ingredients or intermediates used in manufacturing a drug compound, or patents relating to a drug's packaging. *See, e.g.*, Form FDA 3542 (12/08) ("Patent Information Submitted Upon and After Approval of an NDA or Supplement"), *available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048345.pdf.

Similarly, section 271(e)(2)(A) does not provide jurisdiction over method of use patents that do not claim FDA-approved uses. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1354 (Fed. Cir. 2003). Nor does it provide jurisdiction over patents covering approved methods of use where the generic applicant has used the "section viii" carve-out mechanism to remove the approved use from its label. *AstraZeneca Pharms. LP v. Apotex Corp.*, Civil Nos. 10-338, 10-339, 10-340, 10-341, 10-342, 10-343, 10-345, 10-346, 10-584, 10-344, 2010 WL 5376310 (D. Del. Dec. 22, 2010). In *AstraZeneca*, this Court reviewed the question whether a claim could be brought under section 271(e)(2) for two patents covering approved methods of use, even though defendants only sought approval for approved uses not covered by those patents. The Court held that there was no jurisdictional basis for such a claim. *Id.* at *11.

Yet, according to Medicis, as long as there is a Paragraph IV certification to a single patent, there is a jurisdictional basis for suit on **any patent** covering the drug or its use. Clearly, that is not so. Indeed, according to Plaintiff's rationale, not only could it have pursued infringement claims contrary to each of the cases cited above, but it would even have been able to assert a claim for infringement of a patent despite the fact that the ANDA filer did not seek FDA approval until after the patent expired (*i.e.*, a patent for which a Paragraph III certification was filed). Such illogical results show the fatal flaw in Plaintiff's argument.

As set forth in Nycomed's opening brief, the Court should be guided by the district court's decision in *Eisai Co. v. Mutual Pharmaceutical Co.*, No. 06-3613, 2007 WL 4556958 (D.N.J. Dec. 20, 2007). Medicis attempts to distinguish the *Eisai* decision by arguing that the ANDA in question there did not contain a Paragraph IV certification at the time of the complaint. (Medicis Opp. Br. at 10.) However, that is a distinction without a difference. Nycomed's ANDA also did not contain a Paragraph IV certification to the '738 patent when Medicis filed this action, which solely concerns infringement of the '738 patent. The fact that Nycomed's ANDA contained paragraph IV certifications as to other patents, already asserted by Medicis in a different case (and since transferred), is simply irrelevant to whether the statute creates jurisdiction in this case, for this patent to which no Paragraph IV certification has been made.

The cases cited by Medicis in its opposition brief are wholly inapposite. The issue in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), concerned whether an ANDA applicant could be liable for willful infringement by virtue of the filing of an ANDA or Paragraph IV certification. The Federal Circuit held that "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement." *Id.* at 1350-51. The Court did not purport to decide *any* issues relating to the jurisdictional scope of

the statute, noting only in passing that "the act of filing an ANDA constitutes a 'highly artificial' act of infringement." *Id.* at 1349. As Medicis concedes, the Court did not even mention whether the patents-in-suit were subject to Paragraph IV certifications. (Medicis Opp. Br. at 9.) The cases Medicis cites erroneously rely on *Glaxo* for the proposition that the filing of an ANDA itself confers jurisdiction for patent infringement. In fact that was not the holding, or even an issue addressed in *Glaxo*.

In *Teva Pharmaceuticals USA, Inc. v. Abbott Laboratories*, 301 F. Supp. 2d 819 (N.D. Ill. 2004), the ANDA filer itself sought declaratory judgment of invalidity for patents relating to an antibiotic, drugs that at the time were exempt from the patent listing and certification requirements of the Hatch-Waxman Act. The court analyzed jurisdiction under the Declaratory Judgment Act, not whether jurisdiction was appropriate under section 271(e)(2)(A). In *Bayer Healthcare, LLC v. Norbrook Labs, Ltd.*, No. 08-C-0953, 2009 WL 6337911 (E.D. Wis. Sept. 24, 2009), the applicant filed, and then withdrew, its Paragraph IV certification for the only listed patent. Here, by contrast, Nycomed has made no Paragraph IV certification to the '738 patent at all. In *Purdue Pharma Products L.P. v. Par Pharmaceutical Inc.*, 642 F. Supp. 2d 329 (D. Del. 2009), the parties apparently did not contest jurisdiction. Here, of course, Nycomed is contesting jurisdiction.

While Medicis attempts to ignore the real facts in this case, those circumstances further show the flaw in Medicis' interpretation. Nycomed notified Medicis in April 2010 that it had filed its ANDA with Paragraph IV certifications as to the patents then listed in the Orange Book. Medicis filed suit on those patents in May 2010 in a wholly separate action, since transferred by

this Court to the Southern District of New York.[1] The '738 patent at issue in this motion issued on September 14, 2010, and was thereafter listed in FDA's Orange Book. Yet, under Medicis' statutory interpretation, it could have filed its action on the day the '738 patent issued, before that patent was ever listed in the Orange Book. Or, it could have sued on the same day the '738 patent was listed in the Orange Book. In either case, Nycomed would be deprived of the chance to decide whether to file a Paragraph III or Paragraph IV certification, a "carve-out" under section viii, or, for that matter, to withdraw the ANDA entirely.[2] The impropriety of such a result is highlighted even more by the fact that a Paragraph IV certification states that the patent at issue is, in the opinion of the applicant, invalid and/or not infringed. Surely Congress intended that prior to making such a certification the applicant would actually have the opportunity to examine the patent and determine its position and course of action. Statutes should not be interpreted in a way that thwarts Congressional intent and "produces such absurd results." *Dewsnup v. Timm*, 502 U.S. 410, 427 (1992).

B. NO SUBJECT MATTER JURISDICTION EXISTS FOR DECLARATORY JUDGMENT OF INFRINGEMENT UNDER 35 U.S.C. § 271(a)-(c).

Medicis' arguments that declaratory judgment jurisdiction exists here are based on the flawed premise that jurisdiction already exists under section 271(e)(2). As shown above, Medicis has no standing to assert the '738 patent unless and until Nycomed makes a Paragraph

[1] *See Medicis Pharm. Corp. v. Nycomed US Inc. et al.*, Civ. No. 10-419-SLR, D.I. 29 (D. Del. Mar. 31, 2011).

[2] Medicis argues that it has alleged that the FDA will require Nycomed to amend its ANDA to include a Paragraph IV certification. (Medicis Opp. Br. at 10-11.) Medicis mischaracterizes the relevant allegation in its own complaint, which states only that the FDA will require "*a* certification" and not necessarily a Paragraph IV certification. (Compl. ¶ 15.) The FDA could not require a Paragraph IV certification because Nycomed has various options among which it can choose, only one of which is a Paragraph IV certification.

IV certification and notifies Medicis that it has done so. At most, the cases cited by Medicis in support of its declaratory judgment argument stand for the simple proposition that **where jurisdiction already exists under section 271(e)(2)**, jurisdiction also exists for claims of induced and contributory infringement. Indeed, the block quote at page 13 of Medicis' opposition brief from *Cephalon, Inc. v. Watson Pharmaceuticals, Inc.*, 629 F. Supp 2d 338 (D. Del. 2009) states that the Court's consideration of jurisdiction over the section 271(b) and (c) claims was "**[i]n the context of a 271(e)(2) infringement action.**" *Id.* at 351 (emphasis added). As the Court stated in that case, "claims for induced infringement **predicated on § 271(e)(2)**" do not violate the case or controversy requirement of Article III or the Declaratory Judgment Act. *Id.* at 350 (emphasis added).[3]

Medicis likewise points to *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409 (D. Del. 2010), as supporting its declaratory judgment argument. It does not. *Cyclobenzaprine* relies on *Cephalon* for the same proposition: that "[i]n the context of a § 271(e)(2) infringement action" jurisdiction exists over ancillary infringement claims **on the same patent**. *Id.* at 419. Moreover, although Medicis attempts to draw some parallel to the defendants' refusal to provide confidential access to their ANDA in that case, no such parallel can be drawn. Nycomed offered confidential access to the ANDA on an outside counsel basis, provided such counsel did not engage in patent prosecution or FDA

[3] Other cases cited by Medicis as supporting its declaratory judgment argument also must fail, since in those cases declaratory judgment jurisdiction over claims of induced and contributory infringement was likewise predicated on the existence of section 271(e)(2) jurisdiction over those patents. *Bayer*, 2009 WL 6337911, at *13-14; *Takeda Pharms. Co. v. Sandoz, Inc.*, Civ. No. 07 Civ. 3844, 2007 WL 2936208, at *3-4 (S.D.N.Y. Oct. 9, 2007). In *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006 (N.D. Ill. 2001), the drug at issue was a so-called "old antibiotic" to which section 271(e)(2) did not apply.

counseling for Medicis. However, Medicis insisted that its in-house counsel also have access to the ANDA, even though they are also responsible for patent prosecution. Section 355(j)(5)(C)(i)(III) permits the ANDA applicant to impose restrictions on persons who may have access to the ANDA "as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." Nycomed's proposed condition was entirely reasonable and consistent with typical protective orders in such cases. Indeed, in *Cyclobenzaprine* the protective order governing the consolidated actions contained a similar so-called patent prosecution bar on in-house and outside counsel. *See Eurand Inc. v. Mylan Pharms. Inc.*, Civ. No. 1:08-cv-00889-SLR, D.I. 74 (D. Del. July 20, 2009).[4]

Finally, in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330 (Fed. Cir. 2007), the ANDA filer, Teva, brought its action for declaratory judgment on four Orange Book listed patents **after** filing Paragraph IV certifications on each, **after** giving notice to the patentee, and **after** the 45-day period for Novartis to file suit under Hatch-Waxman had passed. According to the Federal Circuit, Teva's suit was specifically authorized by 1) the provisions of the "civil action to obtain patent certainty" under 21 U.S.C. § 355(j)(5)(C); 2) the ANDA declaratory judgment provision under 35 U.S.C § 271(e)(5); and 3) the purpose of the Hatch-Waxman Act. Those facts and statutory provisions are not applicable here. Medicis, the patentee, not the ANDA filer brought suit here. Unlike Teva, Nycomed has not filed a Paragraph IV notice on the patent in suit, has not provided notice to Medicis, and the 45-day period has not

[4] Nycomed remains willing to provide its ANDA to Medicis' counsel on an outside counsel eyes only basis, until such time as the current venue and jurisdictional disputes are ruled on by the Court and an appropriate protective order is issued by either this Court or the Southern District of New York.

run. And, the action to obtain patent certainty of § 355(j)(5)(C) and the ANDA declaratory judgment provision under 35 U.S.C § 271(e)(5) is not the statutory basis for Medicis' action.

Where jurisdiction over an Orange Book listed patent does not exist because no Paragraph IV certification has yet been made, finding declaratory judgment jurisdiction over such a patent would impermissibly interfere with the Hatch-Waxman statutory scheme established by Congress. That scheme establishes an artificial act of infringement of a specific patent by the filing of a Paragraph IV certification on that patent. That action, and only that action, is the key fact that establishes jurisdiction under the statute. Holding that declaratory judgment jurisdiction exists for an Orange Book listed patent in the absence of that all-important first step would permit patentees to circumvent Congress' carefully laid framework. The Court should reject Medicis' argument.

C. THE COURT SHOULD DECLINE TO EXERCISE ITS DISCRETIONARY JURISDICTION OVER THE DECLARATORY JUDGMENT CLAIM

The Court has already transferred Medicis' action on the '001, '424 and '422 patents to the Southern District of New York. As Medicis itself asserts in its opposition, discovery and pretrial motions will now proceed in that district on highly related patents. It makes little sense for Medicis to continue to pursue this action in this Court at this time. Although Nycomed has requested that Medicis voluntarily transfer this action to the Southern District of New York, Medicis has refused. Accordingly, in the interests of judicial economy, if the Court does not transfer this action to the Southern District where it can be consolidated with the action on those related patents, it should exercise its discretion and decline jurisdiction over Medicis' action. If and when Nycomed files a Paragraph IV certification as to the '738 patent, Medicis can then assert its infringement claim in the Southern District.

III. CONCLUSION

For the foregoing reasons, Nycomed respectfully requests that the Court grant its motion to dismiss the complaint in its entirety.

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Dated: April 19, 2011

CERTIFICATE OF SERVICE

I hereby certify that on April 19, 2011, I caused to be filed the foregoing document with the Clerk of Court using CM/ECF, which will send notification of such filing(s), and have sent the foregoing document by electronic mail to the following:

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